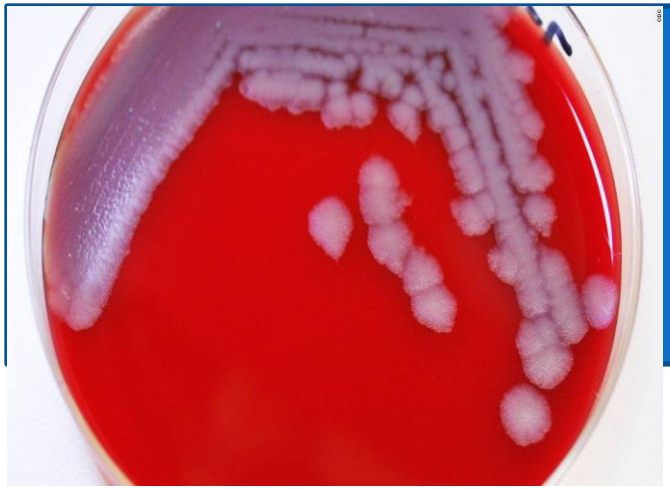
DPHL's Response to DoD Anthrax Event



May-June 2015

CDC – B. anthracis - SBA media

CDC - Influenza (H5N1) Event - **2014**

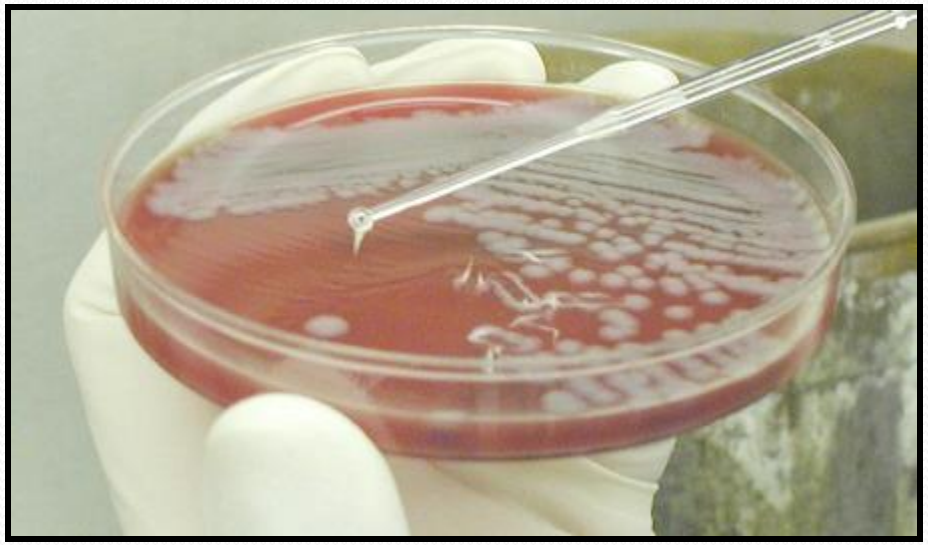
- January 17, 2014
  - CDC Roybal Campus staff inadvertently cross-contaminate low-pathogenic avian influenza (H5N1) virus with high-pathogenic virus
  - Subsequent shipment of culture to external laboratory
- May 23, 2014
  - Error recognized by receiving laboratory
  - Notified CDC
- **Cause** –
  - *"…failure of a laboratory scientist to adhere to established best practices…"*
  - *"…the absence of an approved laboratory team-specific standard operating procedure…"*
- Outcome
  - Closed laboratory
  - Internal inventory of >7,000,000 samples in long-term storage

CDC - Ebola Event - 2014

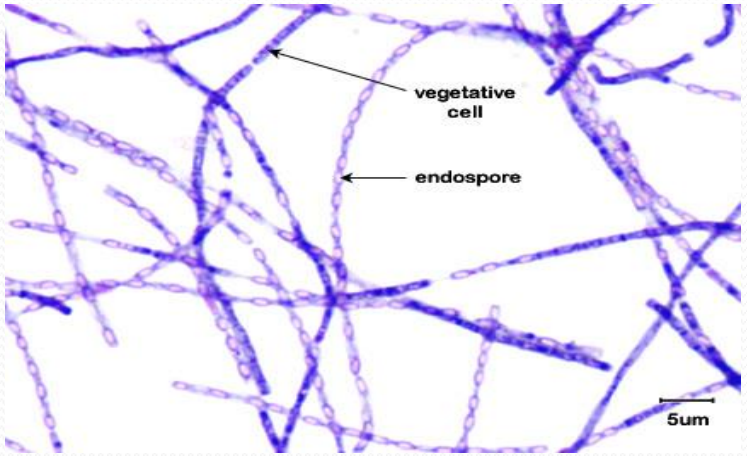
- December 23, 2014
  - CDC discovers potentially live virus in samples
  - Samples sent from BSL4 laboratory to BSL2 laboratory
  - Cause –
    - Misidentification of live vs. inactive sample
    - "*Lack of a study plan to minimize human error*"
  - Outcome
    - Closed BSL4 Laboratory
    - Investigation initiated

Bacillus anthracis

Culture on Sheep Blood Agar

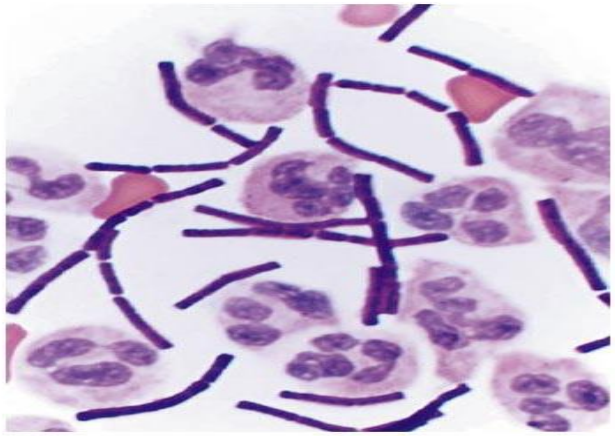


Source – CDC – www.bacteriainphotos.com



Gram stain of older colony

Gram stain of CSF



Bush, et al. 2001. N Engl J Med 345(22):1607-1610

CDC - Anthrax Event - **2014**

- June 5, 2014
  - Scientist in Bioterrorism Rapid Response and Advanced Technology (BRRAT) biosafety level (BSL) 3 laboratory prepares extracts from panel of 8 bacterial Select Agents, including *B. anthracis*
  - Purpose – determine if MALDI-TOF mass spectrometry provides faster way to detect anthrax compared to conventional methods
  - Plate chemically treated & sent out of BSL-3 to BSL-2 labs
- June 13, 2014
  - Another BRRAT BSL-3 scientist observes growth in original anthrax plate
  - **Cause** - Plate treated in chemical solution for 10 minutes rather than 24 hours
- June 18, 2014 - BRRAT lab ceases all operations
- July 11, 2014 – Investigation Report - "*…lack of an approved, written study plan reviewed by senior staff or scientific leadership to ensure that the research design was appropriate and met all laboratory safety requirements.*" (Source - Final Report on the Potential Exposure to Anthrax, CDC, 7/11/2014)

DoD - Anthrax Event - 2015

- Friday, May 22, 2015 (Day 1)
  - Department of Defense (DoD) acknowledges that U.S. Army Dugway Proving Grounds Laboratory inadvertently shipped live anthrax to commercial laboratories
  - Purpose – *"…to develop a rapid diagnostic test for biological threats."*

    (Source - Benjamin Haynes, CDC Spokesman)
  - **Cause** – Failure of irradiation process due to *"…inactivation procedures require more oversight…uncertainty about whether Dugway failed to conduct inactivation or sterility testing…better record keeping and record system are needed"*

    (Source - Testimony by Daniel M. Sosin M.D.M.P.H., informed - CDC Deputy Dir. Office of Health Preparedness & Response, CDC, USDHSS, before the U.S. House of Representatives, Committee on Energy and Commerce, Subcommittee on Oversight and Investigations – *Review of DoD Anthrax Shipments, July 18, 2015)*

Delaware Event Timeline

- Saturday 5/23/15 (Day 2)
  - 01:00 am – Christina Pleasanton, DPHL Deputy Director called by Section Chief for DPH EMS and Preparedness Program – Informed that DoD irradiated vials may contain live Bacillus anthracis (Anthrax) - Shipped to private laboratory in DE
  - Possibly 7 labs in 5 states
  - Private laboratories informed
  - Recovery measures initiated – CDC & EPA involved
  - CDC first recommends culturing vials to determine organism viability
  - DPHL Staff on standby to culture over Memorial Day weekend
  - CDC unclear with instructions
    - Do not culture vials – hold until vials retrieved – Retrieval process to be defined
    - Send Antigen 1 to CDC
    - Other vials - culture to see if viable (Unsure if organisms weaponized or genetically modified)

Delaware Event Timeline

- Sunday 5-24-15 (Day 3)
  - Private laboratory requests support
    - Handling situation
    - Personnel exposure
    - Safety & security of area
    - Securing 39 vials
  - Epidemiology begins investigation of event
- Monday 5-25-15 (Day 4)
  - DPHL requests Select Agent Program permission to take possession of vials
  - FBI approved to retrieve vials & transport (5-26-15)to DPHL

Delaware Event Timeline

- Tuesday 5-26-15 (Day 5)
  - DPHL granted permission by Select Agent Program to take possession of vials
  - FBI transports vials to DPHL
  - One person placed on post exposure antibiotics & follow up (private lab)
- Wednesday 5-27-15 (Day 6)
  - DPHL packages & ship 1 vial Category A to CDC
  - DPHL cultures 4 vials for all BT agents
  - DPHL autoclaves/decontaminates 10 vials of BT agent dilutions
  - 25 vials still in custody (autoclaves/decontaminates later when requested by CDC
  - DoD press release (only mentions anthrax)
- Thursday 5-28-15 (Day 7)
  - DPHL works with 31st Civil Support Team (CST) – collect 14 environmental samples from affected laboratory
  - Environmental cleanup process CDC guidelines in development (EPA, CDC, DoD)

Delaware Event Timeline

- Monday 6-1-15 (Day 11)
  - CDC does not recommend decontamination with Vaporized Hydrogen Peroxide (VHP)
  - CDC Guidance pending
  - DPHL vial cultures completed - No select agent isolated – broths held 7 days (Note - at CDC, DE vial grew wild type anthrax at very low concentration - < 10 spores/vial)
- Wednesday 6-3-15 (Day 13)
  - DPHL environmental sample cultures completed - No select agents isolated
  - CDC decontamination guidelines pending

Delaware Event Timeline

- Monday 6-8-15 (Day 18)
  - DPHL notified of CDC decontamination guidelines
  - Recommends wipe down - Spor –Klenz (EPA approved)
  - Biological spore checks used in fumigation process & cultured
- Friday 6-12-15 (Day 22)
  - Past shipments from DOD identified to contain live Anthrax
  - DPHL given permission by Select Agent Program to have CST to collect & transport these older vials
  - DPHL to destroy vials
- Thursday 6-18-15 (Day 28)
  - CST collects remaining 41 vials from laboratory (past yrs.) & transports to DPHL
  - Vials destroyed
  - Wipe-down decontamination of lab completed
  - In-tent fumigation of equipment – para-formaldehyde; done by DPH & DNREC

Outcomes & Lessons Learned

Wednesday 6-24-15 (Day 34)–DPHL Hot Wash (DPHL, CST, DNREC ERB, HSP)

- Challenges
  - Not expecting potentially infectious agent event
  - BSL 1 – open work areas, no doors, no biosafety cabinet, vortexed the sample on an open bench
  - Unknown strain of anthrax (weaponized? wild type? attenuated? modified?)
  - Extraction of vials
    - Potentially contaminated laboratory
    - Who extracts vials from lab?
    - What PPE needed?
  - Transport issues
    - Not certified to ship Class-A
    - Transport requirements (local, interstate)
    - Who transports? (FBI, CST, DNREC, DPHL, other?)
  - Decontamination issues
    - Environmental decontamination
    - Instrument decontamination
    - Spore check – use of proper spore check organism (company recommends wrong organism – *Geobacillus stearothermophilis*)
  - Loss of business & employees out-of-work due to closure
  - Families concerned about possible exposure

Outcomes & Lessons Learned

- CDC & EPA & DoD not readily forthcoming with decontamination guidance
- CDC - Initial "do bleach wipe down" then EPA intercedes – "… use EPA approved labeled product" OR apply for EPA waiver to go "off Label"
- Inter-agency (CDC, EPA, DoD, etc.) involvement cause delays, confusion, and non-action

- DPHL & Partners
  - Communications
    - Need greater detail especially at onset
    - Need to eliminate intermediary contacts
  - Trust - key factor in inter-organizational work
  - Delaware - first state to decontaminate a laboratory after this type of exposure
  - Shipping of Select Agents remains unresolved
  - Overtime work
  - Specimen count
    - Initial panel – 29
    - Final count
      - Vials – 102
      - Environmental samples – 20
      - PT round samples - 14
      - Spore Check samples – 45
    - Total count - 181

THANK YOU !